

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
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MARYLOU SUDDERS Secretary

> Margret Cooke Commissioner

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Board of Registration in Pharmacy

Policy 2022-06: COVID-19 Therapeutics

The Massachusetts Department of Public Health ("DPH"), through the Board of Registration in Pharmacy ("Board"), authorizes the ordering, dispensing, and administration of certain COVID-19 therapeutics in accordance with the Secretary of Health and Human Services' Declaration under the PREP Act and this policy.

Pharmacists may order, dispense, and administer, and pharmacy interns and qualified pharmacy technicians may administer, any Food and Drug Administration ("FDA")-approved, authorized, cleared, or licensed **COVID-19 therapeutics** to populations authorized by the FDA and Centers for Disease Control and Prevention ("CDC") and in accordance with this policy.

Although qualified pharmacy personnel are authorized to administer COVID-19 therapeutics to ages 3 years and older, refer to specific manufacturer information, FDA and CDC guidelines for product-specific age groups.

I. General Requirements

Product-specific requirements are outlined below in Section II

A. Ordering

Pharmacists may order and dispense or administer COVID-19 therapeutics when the following criteria are met:

- a. the COVID-19 therapeutic must be approved, authorized, cleared, or licensed by the FDA;
- b. ordering COVID-19 therapeutics must be done in accordance with <u>Information for Providers about Therapeutic Treatments for COVID-19</u> issued by DPH;

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- c. if the therapeutic has an Emergency Use Authorization ("EUA"), it must specifically allow ordering by a pharmacist;
- d. routes of administration are limited to subcutaneous, intramuscular, and oral, and only in accordance with the FDA approval, authorization, clearance, or licensing, including any applicable conditions of use that may apply (e.g., pregnancy screening, laboratory blood work, etc.);
- e. pharmacists must generate a patient-specific prescription prior to dispensing or administration. Pharmacists may only order an eligible product in accordance with manufacturer approved labeling and age groups for the specific product to be dispensed or administered; and
- f. the licensed pharmacist must comply with any state or federal recordkeeping and reporting requirements, including informing the patient's primary-care provider when available.

B. Administering

Pharmacists, pharmacy interns, and qualified pharmacy technicians may administer COVID-19 therapeutics when the following criteria are met:

- a. the therapeutic may only be administered subcutaneously or intramuscularly and only in accordance with the FDA approval, authorization, clearance, or licensing;
- compliance with any state or federal requirements, including recordkeeping, adverse event reporting, and informing the patient's primary-care provider when available;
- c. compliance with any applicable conditions of use (e.g., pregnancy screening);
- d. appropriate private space (e.g., counseling / immunization room) based on the nature of administration (e.g., gluteal injection);
- e. clinical monitoring and observation (e.g., 1 hour) of individuals after administration in accordance with manufacturer's instructions; and
- f. ACPE-approved training must be completed that includes:
 - i. for pharmacists and pharmacy interns:
 - a. requirements as outlined in <u>Policy 2020-11: Vaccine</u>
 <u>Administration</u> to include competency in intramuscular gluteal administration (as applicable); and
 - b. clinical evaluation of indications and contraindications:
 - ii. <u>for qualified pharmacy technicians</u>, requirements as outlined in <u>Policy 2020-12</u>: <u>Vaccine Administration by Qualified Pharmacy Technicians</u> to include competency in intramuscular gluteal administration (as applicable);
 - iii. for all qualified pharmacy personnel:

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- a. recognition and treatment of emergency reactions; and
- b. any additional training required in the FDA approval, authorization, clearance, or licensing.

II. PAXLOVID™ (nirmatrelvir and ritonavir)

- A. <u>Pharmacists may prescribe Paxlovid™</u> with certain limitations as described below. Carefully review DPH's <u>Paxlovid™ Treatment Guidance</u> prior to prescribing.
- B. Pharmacists may prescribe Paxlovid[™] to patients who have tested positive for COVID-19 upon review of sufficient information to determine patient eligibility for Paxlovid[™] including assessing kidney or liver problems and obtaining a list of all medications, including over-the-counter medications to screen for drug interactions. This information can be accessed through one of the following:
 - a. Patient-provided electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work that would indicate kidney or liver problems, and a list of all medications, including over-the-counter medications.
 - b. Pharmacist consultation with the patient's health care provider.
- C. Pharmacists and pharmacies must establish appropriate facility provisions (e.g., segregated area, drive through, etc.) and precautions (i.e., <u>donning appropriate personal protective equipment</u>) for consulting with patients who have tested positive for COVID-19 in order to reduce the risk of transmission.
- D. Under the limitations outlined in the EUA, patients should be referred for clinical evaluation with a practitioner if any of the following apply:
 - a. Sufficient information is not available to assess renal and hepatic function.
 - b. Sufficient information is not available to assess for a potential drug interaction.
 - c. Modification of other medications is needed due to a potential drug interaction.
 - d. Paxlovid[™] is not an appropriate therapeutic option based on the current <u>Fact Sheet for Healthcare Providers</u> or due to potential drug interactions for which recommended monitoring would not be feasible.

Please direct any questions to: Pharmacy.Admin@mass.gov

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